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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,486

04/09/2007

Darrell Sleep

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3066

25908 7590 12/08/2009  
NOVOZYMES NORTH AMERICA, INC.  
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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

NOTIFICATION DATE

DELIVERY MODE

12/08/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,486	<b>Applicant(s)</b> SLEEP ET AL.	
	<b>Examiner</b> James S. Ketter	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45,47 and 64-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45,47 and 64-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2006 and 20 September 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/24/2009</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 8-10 and 17-47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the previous Office Action.

At page 12 of the amendment filed 21 September 2009, Applicants argue that they have presented a representative number of examples of 2 micron plasmids, and that they have taught the characteristics thereof, including a diagram. However, for reasons of record set forth in the grounds of the rejection, the genus is very broad, with no significant features in common beyond the presence of inverted repeats and a recombinase gene. Applicants go on, through page 13, to argue that a circular plasmid from yeast is a 2 micron plasmid, and that no evidence has been presented that Applicants had not adequately described the claimed invention. However, small circular chromosomes, and the overlapping plasmids designated CEN plasmids from yeasts, are circular, represent a vast and varied genus, and yet are not designated 2 micron plasmids in the art. If all circular plasmids from yeast are included in the genus encompassed by the instant claims, then this vast, varied genus of CEN plasmids and circular chromosomes must also be encompassed, for which there is clearly no description presented in the specification. With respect to the question of evidence presented in support of the rejection, it is maintained that the reasoning presented in the previous Office Action, as well as the response to Applicants'

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arguments in the present Office Action, are evidence, based on reasoned scientific analysis of Applicants' own disclosure, coupled with questions posed by the prior art existence of seemingly non-2 micron plasmids from yeasts.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-45 and 47 stand, and newly added 64-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record set forth in the previous Office Action.

The rejection stands particularly with respect to the recitation of "2 $\mu$ m-family plasmid". It is maintained that the metes and bounds of the instant claims are unclear. Applicants argue, at page 14 of the amendment, applicants argue that "[o]ne of ordinary skill in the art understands that a 2 $\mu$ m-family plasmid is any circular plasmid obtained from yeast. All of the identified circular plasmids have been classified as 2 $\mu$ m-family plasmids." However, as set forth above, in the discussion of the rejection under 35 USC 112, first paragraph, there are other known types of plasmids from yeasts which are and were not regarded as 2 micron plasmids. However, based on the definition now offered by Applicants, and the two other conflicting definitions as noted in the previous Office Action, the metes and bounds of the claimed invention would not have been clear to one of skill in the art at the time of filing. The discussion offered in Volkert et al. is

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cumulative to the information in the specification or from Applicants arguments on the record, and does not clarify the conflicting definitions of the metes and bounds of the invention.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK

4 December 2009

/James S. Ketter/

Primary Examiner, Art Unit 1636